



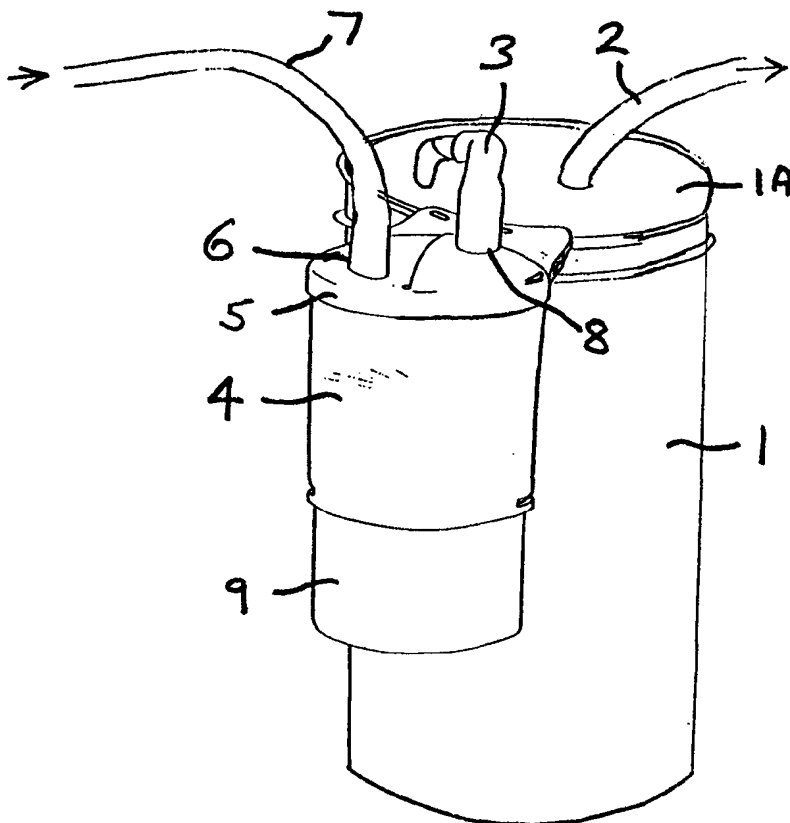
## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(54) Title: APPARATUS FOR SEPARATING TISSUE FROM ASPIRATES

## (57) Abstract

Apparatus for separating tissue from aspirates during evacuative medical procedures, the apparatus comprising: a separation vessel (14) arranged for use in an upright position with an upwardly facing mouth; a removable lid (5) for closing the mouth of the separation vessel (14), the lid (5) having a first port (6) for connection to a source of aspirates and a second port (8) to which suction can be applied and through which liquid from the aspirates can be drawn into a separate collection vessel (1); and a filter screen (10) dividing the interior of the separation vessel into two portions, a first portion (4A) in communication with the first port (6) and a second portion (4B) in communication with the second port (8), so that liquid within the aspirates is able to pass from the first portion (4A) into the second portion (4B), from which it can be drawn out through the second port (8), and tissue within the aspirates is retained within the first portion (4A) so as to be readily accessible therein upon removal of the lid (5).



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## APPARATUS FOR SEPARATING TISSUE FROM ASPIRATES

### TECHNICAL FIELD

This invention relates to apparatus for separating tissue from aspirates during evacuative medical procedures, e.g. uterine evacuation during the termination of a pregnancy.

In conventional apparatus for evacuation of the uterus, aspirates are drawn through a tube into a fluid collection vessel. A separation device, such as a gauze sack is fitted to the inlet port of the vessel to collect any tissue in the aspirates. When the procedure is terminated, the lid of the vessel is removed, the gauze sack detached therefrom and then immersed in a preserving liquid, e.g. a 10% formalin phosphate solution, to preserve the tissue for subsequent transport to a pathologist for examination.

This procedure has disadvantages as it requires nursing or theatre staff to be in contact with the sack when removing it from the collection vessel and then immersing it in preserving solution. Such contact carries the risk of infection, e.g. from hepatitis or AIDS. Furthermore, the same personnel are exposed to the preserving liquid in this process. This is also undesirable and tighter restrictions on the use of materials such as formalin are expected in the near future.

In another known arrangement a separation vessel has been provided externally of the collection vessel but the arrangement still suffers from significant potential for exposure of staff to the aspirates and to formalin and is also prone to accidental breakage.

The present invention seeks to alleviate these problems.

It should be noted that the term "tissue" as used herein should be understood to cover any tissues, particles or other solid matter within the aspirates.

### DISCLOSURE OF INVENTION

According to the present invention, there is provided apparatus for separating tissue from aspirates during evacuative medical procedures, the apparatus comprising: a separation vessel arranged to be used in an upright position with an upwardly facing mouth; removable closure means for closing the mouth of the separation vessel, the closure means having a first port for connection to a source of aspirates and a second port by means of which suction can be applied to the interior of the separation vessel and through which liquid from the aspirates can be drawn into a separate collection vessel; and a filter screen for dividing the interior of the separation vessel into a first portion in communication with the first port and a second portion in communication with the second port, so that liquid within the aspirates is able to pass from the first portion into the second portion, from which it can be drawn out through the second port, and tissue within the aspirates is retained within the first portion so as to be readily accessible therein upon removal of the closure means.

Other features of the invention will be apparent from the following description and from the subsidiary claims of the specification.

### BRIEF DESCRIPTION OF DRAWINGS

The invention will now be further described, merely by way of example, with reference to the accompanying drawings, in which:

Figure 1 is a perspective view of an embodiment of apparatus according to the present invention comprising a separation vessel attached to a collection vessel;

Figure 2 is a cross-sectional view of a first embodiment of a separation vessel according to the invention and shows a preservative container mounted for transferring preservative into the separation vessel;

Figure 3 is a cross-sectional view of a second embodiment of a separation vessel according to the invention;

Figure 4 shows the separation vessel of Figure 3 with a preservative container attached to the base thereof;

Figure 5 shows the separation vessel of Figure 3 with a preservative container mounted for transferring preservative into the separation vessel;

Figures 6A - 6D are more detailed views of the connection between the preservative container and the separation vessel of Figure 5 to illustrate features of the connection; and

Figure 7 is an enlarged, cross-sectional view of the attachment between a separation vessel and a collection vessel.

#### BEST MODE FOR CARRYING OUT THE INVENTION

Figure 1 shows a collection vessel 1 having a lid 1A with two ports. One port is connected via a pipe 2 to a vacuum or suction pump the other port is connected via a pipe 3 to a separation vessel 4.

The separation vessel 4 is mounted to the side of the collection vessel 1, e.g. by being clipped thereto, so as to be securely supported in an upright position. The separation vessel 4 has a removable lid 5 which closes the upwardly facing mouth of the vessel 4. The lid 5 is provided with two ports, a first port 6 connected via a pipe 7 to a source of aspirates and a second port 8 connected to the collection vessel 1 via the pipe 3.

The separation vessel 4 is preferably attached to the side of the collection vessel 1 by attachment means provided on the side of the vessel 4 and/or the lid 5 thereof as will be described further below with reference to Figure 7.

A preservative container 9 (to be described further below) is removably secured, e.g. by a snap or push fitting, to the base of the separation vessel 4.

Figure 2 shows a cross-section of a first embodiment of a separation vessel 4 with the preservative container mounted to the port 6 for transferring preservative into the vessel 4. The interior of the separation vessel 4 is divided into two portions by a filter screen 10, a first portion 4A in communication with the first port 6 and a second portion 4B in communication with the second port 8.

In use, the separation vessel is first connected as illustrated in Figure 1 and aspirates enter the first portion 4A of separation vessel 4 through the port 6. Liquid within the aspirates is able to pass through the filter screen 10 to the second portion 4B of the vessel, from which the liquids are sucked out via a dip pipe 11 through the second port 8 to the collection vessel 1. Any tissue within the aspirates is retained in portion 4A of the vessel by the filter screen 10 and so is not sucked into the collection vessel 1.

The separation vessel 4 is preferably shaped so as to have a sump at the base of the portion 4B. The dip pipe 11 extends towards the bottom of the sump and so ensures that the majority of liquid in the portion 4B is sucked into the collection vessel 1 and the tissue retained in portion 4A left relatively dry.

On completion of the evacuation procedure, the pipes 3, 4D and 7 are removed from the ports 6 and 8 and the preservative container 9 removed for its mounting at the base of the separation vessel 4 and fitted onto the first port 6

as illustrated in Figure 2. A closure cap 12 removed from a nozzle 13 of the container 9 during this procedure may be used to close the second port 8 of the vessel 4 as shown in the Figure.

The container 9 is inverted with its nozzle 13 in engagement with the first port 6 of the vessel 4. Preservative solution in the container 9 can then be passed through the port 6 into the vessel 4 to cover any tissue retained therein.

The separation vessel 4 can then be stored or transported to another location or site, for example to a pathology laboratory, preferably with the container 9 still mounted on the port 6 as shown in Figure 2.

Once in the pathology laboratory, a pathologist can remove the lid 5, with container 9 attached thereto, from the separation vessel 4 whereupon the tissues retained therein are readily accessible for removal and/or examination.

As illustrated, the mouth of the vessel 4 and the lid 5 preferably extend across the entire width of the vessel 4 to provide easy access to its interior.

The lid 5 preferably has an O-ring seal 5A so it is readily re-sealable when replaced on the vessel 4 and is preferably attached to the vessel 4 by means of a bayonet or other fitting which requires positive action to release the lid from the vessel 4. The vessel 4 can thus be re-sealed after use prior to its disposal.

As shown in Figure 2, the lid 5 is positively secured to the vessel 4 by engagement with projections 4C provided on the vessel 4. These projections 4C may comprise part of a snap fit attachment, a bayonet fitting or some other attachment means.

It will be appreciated that the design of the apparatus described above is such as to minimise exposure of nursing or theatre staff firstly to the aspirates

collected in the vessel 4 and, secondly to the preservative solution subsequently transferred into the vessel 4.

The separation vessel 4 can be easily detached from the collection vessel 1 and the risk of leakage or spillage from the vessel 4 is minimised as it is used in an upright position with an upwardly facing mouth and because both the ports 6 and 8 are provided on the lid which closes the mouth of the vessel. There is, therefore, no danger of leakage of the aspirates from the vessel 4 when the pipes 3 and 7 are removed. Furthermore, the vessel 4 is securely mounted to the side of the collection vessel 1 so if either vessel is accidentally knocked, the direct physical attachment between the vessels helps ensure that the fluid connection via pipe 3 is not dis-lodged.

The separation vessel 4 can be stored or transported after detachment from the collection vessel 1 so there is no need for the nursing staff to open the separation vessel or be exposed to the tissues retained therein.

The preservative container 9 is preferably charged with preservative in the pathology laboratory before the aspiration procedure takes place so merely needs to be connected to the separation vessel 4 by the nursing or theatre staff as shown in Figure 2. The nursing and theatre staff are not, therefore, exposed to the preservative solution.

In the arrangement shown in Figure 2, the container 9 is provided with a simple cap 15 and a rupturable seal 16 which is pierced by projections provided at the distal end of spigot 14 extending from the lid 5.

However, the connection between the preservative container 9 and the first port 6 of the vessel 4 is preferably designed so that the quantity of preservative solution passed into the vessel 4 can be controlled by the nursing or theatre



staff. This form of connection will now be described further with reference to Figures 3 - 6.

Figure 3 shows a second embodiment of a separation vessel 4. This vessel is similar to that shown in Figure 2 but has a different form of spigot 14 extending from the lid 5. The mounting 4D for securing the preservative container 9 to the base of the vessel 4 is also of a different design.

Figure 4 shows the separation vessel 4 of Figure 3 with a preservative container 9 fitted to the mounting 4D at the base thereof. As shown, the container 9 is held in the mounting 4D in an upright position ready for use.

Figure 5 shows the collection vessel 4 of Figure 3 after the preservative container 9 has been removed from the mounting 4D, inverted and fitted onto the spigot 14.

Figures 6A - 6D illustrate the manner in which the connection between the preservative container 9 and the spigot 14 operates to allow the quantity of preservative transferred to the collection vessel 4 to be controlled.

Figure 6A shows the hollow spigot 14 attached to the first port 6 of the vessel 4, the spigot having a hole 14A formed through the wall thereof towards the distal end of the spigot. Figure 6A also shows a cap 15 which screws onto the nozzle 13 of preservative container 9 (see Figure 4). The cap 15 is provided with an internal passageway 15A which extends into the nozzle 13 of the container 9. A seal cap 17 is mounted in the passageway 15A and through holes 18 are provided through the walls of the passageway 15A as shown.

As the preservative container 9 is pushed onto spigot 14, the spigot 14 first comes into radial engagement with the internal walls of passageway 15A thereby effecting a continuous sealed connection between container 9 and

separation vessel 4 as shown in Figure 6B. As the container 9 is pushed further onto the spigot 14, the seal cap 17 engages in and seals the end of the spigot 14 as shown in Figure 6C. Then, when the container 9 is pushed yet further onto the spigot 14, the through holes 14A and 18 are brought to the same level (as shown in Figure 6D) so by twisting the container 9 on the spigot 14 they can be brought into alignment to provide communication between the interior of the container 9 and the interior of the vessel 4 so that preservative solution flows into the vessel 4. When sufficient preservative solution has flowed into the vessel 4 to cover the tissues retained therein, the container 9 is twisted to move the holes 14A and 18 out of alignment to stop the flow of preservative.

As shown in Figure 6D, once the container 9 has been pushed fully onto the spigot 14, the distal end of passageway 15A relaxes into a recess behind a detent 14B provided at the end of spigot 14 to hold the container 9 on the spigot 14 and resist any attempt to remove it therefrom.

Other forms of control means or valves may be used to control the quantity of preservative solution passed into the vessel 4. The container 9 may, for instance, be simply connected to the first port 6 of the vessel 4 by a flexible pipe (not shown) and the container 9 squeezed to pass the required quantity of preservative solution into the vessel 4.

As mentioned above, the separation vessel 4 is preferably designed so as to provide a mounting 4D for storage of the preservative container 9 prior to use and to protect it from accidents. It may, for example, be fitted with a mounting 4D extending from the base of the vessel 4 as shown in Figures 1 - 5. The mounting 4D may have an open side, as shown in Figures 3 - 5, to provide easier access to the container 9. The container 9 is preferably removably secured to the mounting 4D by a snap, push or sliding fit. The fitting should be such as to avoid any danger of inadvertently detaching the vessel 4 from its lid

5 or detaching the vessel 4 from the collection vessel 1 when the preservative container 9 is removed from the mounting 4D.

Figure 7 is a cross-sectional view illustrating one form of connection between the separation vessel 4 and a collection vessel 1. As shown in Figure 7, the lid 5 of the vessel 4 is provided at at least one side thereof with a part-circumferential recess 5B which is a push fit onto a circumferential rim or edge 1A of the collection vessel 1. The lid 5 is also preferably provided with a stabilising tongue 5C which projects downwardly and engages against the side of the collection vessel 1 to help hold the separation vessel 4 in a stable position against the collection vessel 1. In a preferred arrangement, the tongue 5C also passes through an aperture 1B provided in a flange or handle projecting laterally from the rim of the collection vessel 1 as shown in Figure 7.

The separation vessel 4 would usually be designed for a single use only and then disposed of by incineration. The preservative container 9 may similarly be for single use or may be re-used. In the latter case, the container 9 may, for instance, be re-used once it has been unscrewed from its cap 15 and fitted with a new cap.

Both the vessel 4 and container 9 are preferably made of a plastics material, e.g. polycarbonate.

The separation vessel 4 is preferably shaped so that it can be stood on a flat surface (whether or not a preservative container 9 is attached to the base thereof) in a stable manner and in an upright position.

Instead of being clipped to the side of the collection vessel 1, the separation vessel 4 may be supported in an upright position by other means, e.g. by a stand.

The filter screen 10 preferably has a cylindrical form as shown in Figure 2 and comprises a mesh affixed or mounted on or about a framework. The mesh size should be selected according to the particular application so as to retain the majority of the tissues in the portion 4A. If the pore size is too large, tissues may pass through the mesh or may become stuck in the pores so making it difficult to remove them for examination. If the pore size is too small, the pores may become blocked and prevent passage of fluids through the screen. A filter screen having pores with a diameter in the range 800-1400 microns is typically found suitable for uterine evacuation procedures.

The apparatus comprising the vessel 4 with its lid 5 and preservative container 9 are preferably provided in a package (not shown), e.g. a cardboard or plastics container. The package is preferably shaped so that not only is it suitable for housing the apparatus in its initial configuration prior to use, e.g. as shown in Figure 4, but it can also be used to house the apparatus in its final configuration after use, e.g. as shown in Figure 5. The package thus provides additional protection for the apparatus when it is stored and then transported to another site by containing it, keeping it upright and helping prevent disengagement of the container 9 from the spigot 14.

CLAIMS

1. Apparatus for separating tissue from aspirates during evacuative medical procedures. the apparatus comprising: a separation vessel arranged to be used in an upright position with an upwardly facing mouth; removable closure means for closing the mouth of the separation vessel, the closure means having a first port for connection to a source of aspirates and a second port by means of which suction can be applied to the interior of the separation vessel and through which liquid from the aspirates can be drawn into a separate collection vessel; and a filter screen for dividing the interior of the separation vessel into two portions, a first portion in communication with the first port and a second portion in communication with the second port, so that liquid within the aspirates is able to pass from the first portion into the second portion, from which it can be drawn out through the second port, and tissue within the aspirates is retained within the first portion so as to be readily accessible therein upon removal of the closure means.
2. Apparatus as claimed in Claim 1 in which the separation vessel and/or the closure means thereof are provided with attachment means for releasably mounting the separation vessel to the side of a collection vessel.
3. Apparatus as claimed in Claim 1 or 2 in which the separation vessel is shaped so that it can be stood on a flat surface in a stable manner and in an upright position.
4. Apparatus as claimed in Claim 1, 2 or 3 in which the mouth of the separation vessel extends across substantially the entire width of the vessel.

5. Apparatus as claimed in any preceding claim in which the separation vessel can be re-sealed by the closure means when the closure means is re-fitted thereto.
6. Apparatus as claimed in any preceding claim in which the filter screen has a substantially cylindrical shape.
7. Apparatus as claimed in any preceding claim in which the filter screen comprises a mesh affixed or mounted on or about a framework.
8. Apparatus as claimed in any preceding claim in which the separation vessel is shaped so as to have a sump at the base of the second portion thereof.
9. Apparatus as claimed in any preceding claim in which a dip tube extends from the second port towards the bottom of the separation vessel.
10. Apparatus as claimed in any preceding claim in combination with a preservative container.
11. Apparatus as claimed in Claim 10 in which the preservative container can be removably attached to the separation vessel for storage.
12. Apparatus as claimed in Claim 11 in which the preservative container fits into a mounting provided on the base of the separation vessel.
13. Apparatus as claimed in any of Claims 10 to 12 in which the preservative container and the first port of the separation vessel have mutually connectable fittings which, when engaged, enable preservative to be passed from the preservative container into the separation vessel.

14. Apparatus as claimed in Claim 13 in which said fittings include a rupturable seal.
15. Apparatus as claimed in Claim 13 or 14 in which said fittings include control means whereby the quantity of preservative passing from the preservative container to the separation vessel can be controlled.
16. Apparatus as claimed in Claim 13, 14 or 15 in which the preservative container has closure means which, when said mutually engageable fittings are engaged, can be used to close the second port of the separation vessel.
17. Apparatus as claimed in Claim 2 or any claim dependent thereon, in which the attachment means are provided at at least one side of the closure means and arranged to mount the separation vessel on a rim of a collection vessel and/or a flange or handle projecting therefrom.
18. Apparatus as claimed in Claim 17 in which the attachment means comprise a recess shaped to be a push fit onto the rim of a collection vessel.
19. Apparatus as claimed in Claim 17 or 18 in which the attachment means comprising a tongue for engaging the side of a collection vessel to help hold the separation vessel in a stable position thereagainst.
20. Apparatus as claimed in Claim 19 in combination with a collection vessel, the collection vessel having a flange or handle projecting laterally therefrom with an aperture through which the tongue fits.

**AMENDED CLAIMS**

[received by the International Bureau on 1 September 1998 (01.09.98);  
original claims 1 and 10-20 replaced by amended claims 1 and 10-18;  
remaining claims unchanged (3 pages)]

1. Apparatus for separating tissue from aspirates during evacuative medical procedures in combination with a preservative container, the apparatus comprising: a separation vessel arranged to be used in an upright position with an upwardly facing mouth; removable closure means for closing the mouth of the separation vessel, the closure means having a first port for connection to a source of aspirates and a second port by means of which suction can be applied to the interior of the separation vessel and through which liquid from the aspirates can be drawn for collection in a separate collection vessel; and a filter screen for dividing the interior of the separation vessel into two portions, a first portion in communication with the first port and a second portion in communication with the second port, so that liquid within the aspirates is able to pass from the first portion into the second portion, from which it can be drawn out through the second port, and tissue within the aspirates is retained within the first portion so as to be accessible therein upon removal of the closure means, the preservative container and the first port of the separation vessel have mutually connectable fittings which, when engaged, enable preservative to be passed from the preservative container into the separation vessel.
2. Apparatus as claimed in Claim 1 in which the separation vessel and/or the closure means thereof are provided with attachment means for releasably mounting the separation vessel to the side of a collection vessel.
3. Apparatus as claimed in Claim 1 or 2 in which the separation vessel is shaped so that it can be stood on a flat surface in a stable manner and in an upright position.



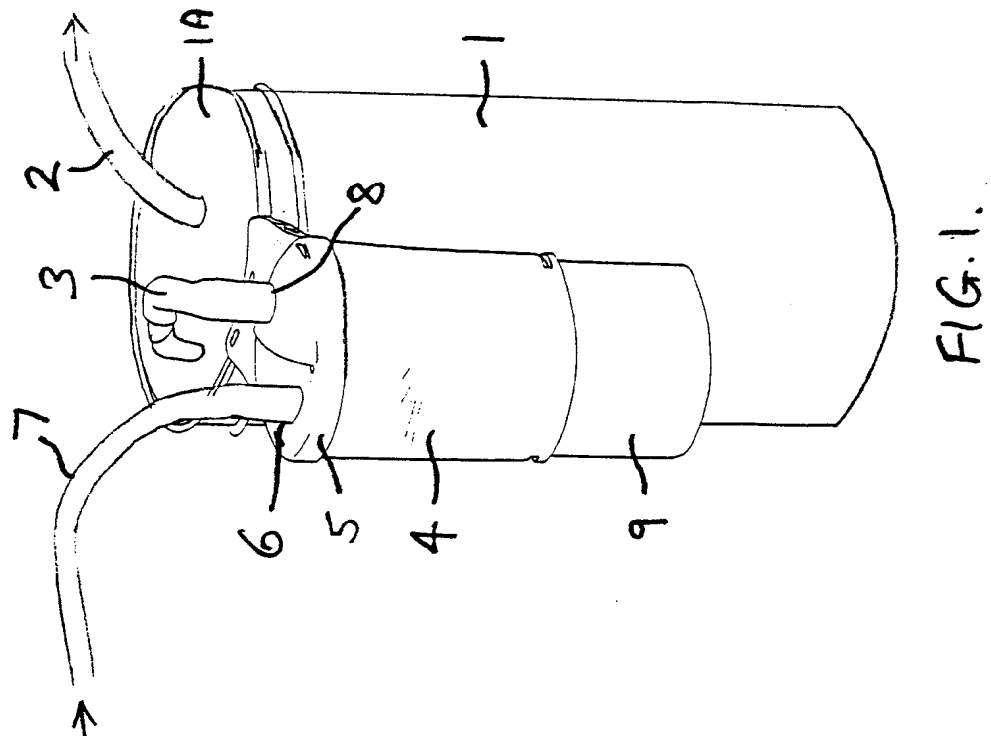
4. Apparatus as claimed in Claim 1, 2 or 3 in which the mouth of the separation vessel extends across substantially the entire width of the vessel.
5. Apparatus as claimed in any preceding claim in which the separation vessel can be re-sealed by the closure means when the closure means is re-fitted thereto.
6. Apparatus as claimed in any preceding claim in which the filter screen has a substantially cylindrical shape.
7. Apparatus as claimed in any preceding claim in which the filter screen comprises a mesh affixed or mounted on or about a framework.
8. Apparatus as claimed in any preceding claim in which the separation vessel is shaped so as to have a sump at the base of the second portion thereof.
9. Apparatus as claimed in any preceding claim in which a dip tube extends from the second port towards the bottom of the separation vessel.
10. Apparatus as claimed in any preceding claim in which the preservative container can be removably attached to the separation vessel for storage.
11. Apparatus as claimed in Claim 10 in which the preservative container fits into a mounting provided on the base of the separation vessel.
12. Apparatus as claimed in any preceding claim in which the mutually connectable fittings include a rupturable seal.

13. Apparatus as claimed in any preceding claim in which the mutually connectable fittings include control means whereby the quantity of preservative passing from the preservative container to the separation vessel can be controlled.
14. Apparatus as claimed in any preceding claim in which the preservative container has closure means which, when the mutually engageable fittings are engaged with each other, can be used to close the second port of the separation vessel.
15. Apparatus as claimed in Claim 2 or any claim dependent thereon, in which the attachment means are provided on at least one side of the closure means and arranged to mount the separation vessel on a rim of a collection vessel and/or a flange or handle projecting therefrom.
16. Apparatus as claimed in Claim 15 in which the attachment means comprise a recess shaped to be a push fit onto the rim of a collection vessel.
17. Apparatus as claimed in Claim 15 or 16 in which the attachment means comprising a tongue for engaging the side of a collection vessel to help hold the separation vessel in a stable position thereagainst.
18. Apparatus as claimed in Claim 17 in combination with a collection vessel, the collection vessel having a flange or handle projecting laterally therefrom with an aperture through which the said tongue fits.

**STATEMENT UNDER ART 19**

The amended claims are directed towards a combination of a separation vessel and a preservation container having mutually connectable fittings which, when engaged, enable preservative to be passed from the preservative container into the separation vessel.

None of the cited prior art discloses such a combination and, as discussed in the application, the claimed arrangement avoids exposing nursing or theatre staff either to the aspirates collected or to the preservative solution.



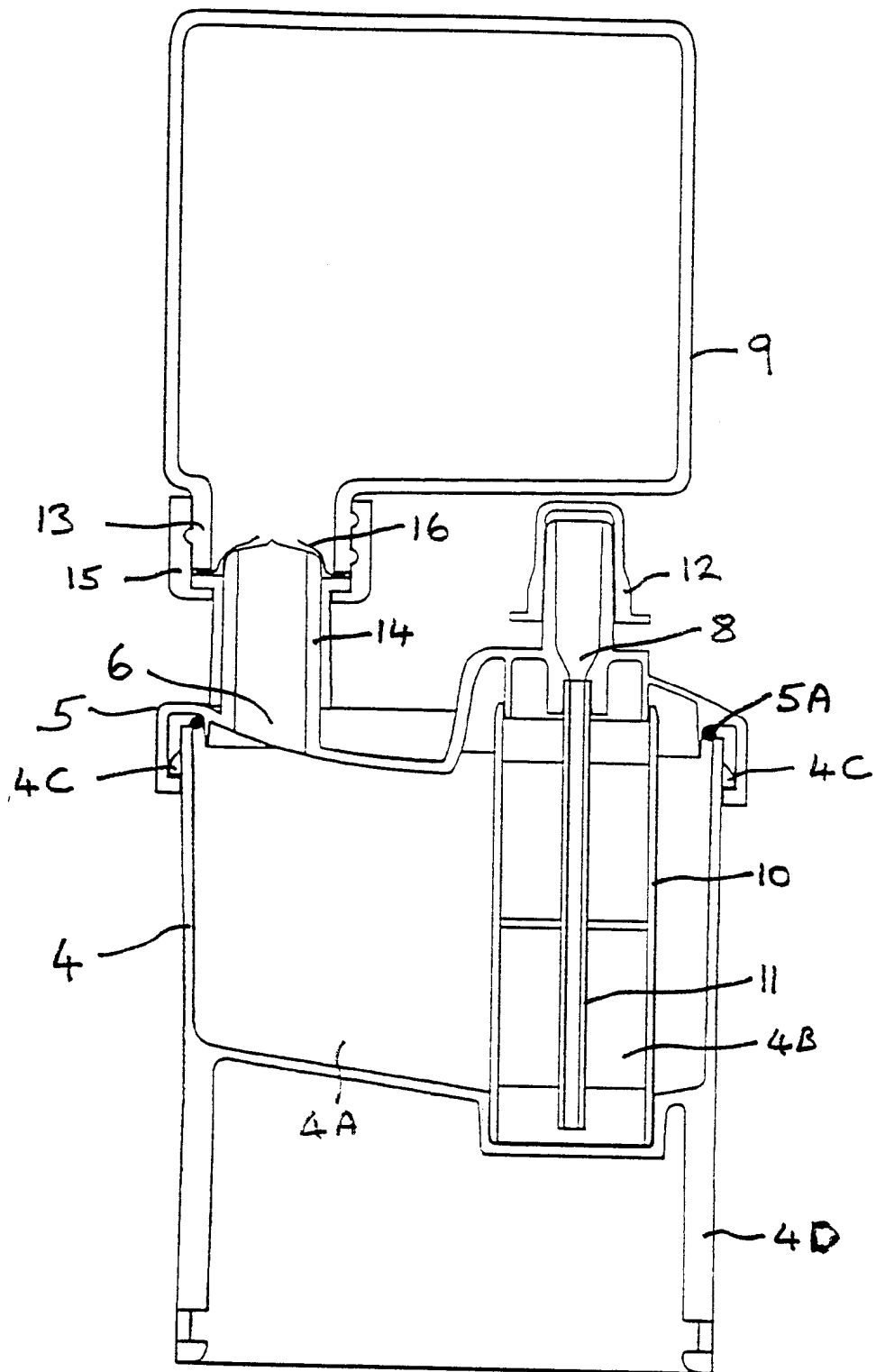


FIG. 2.

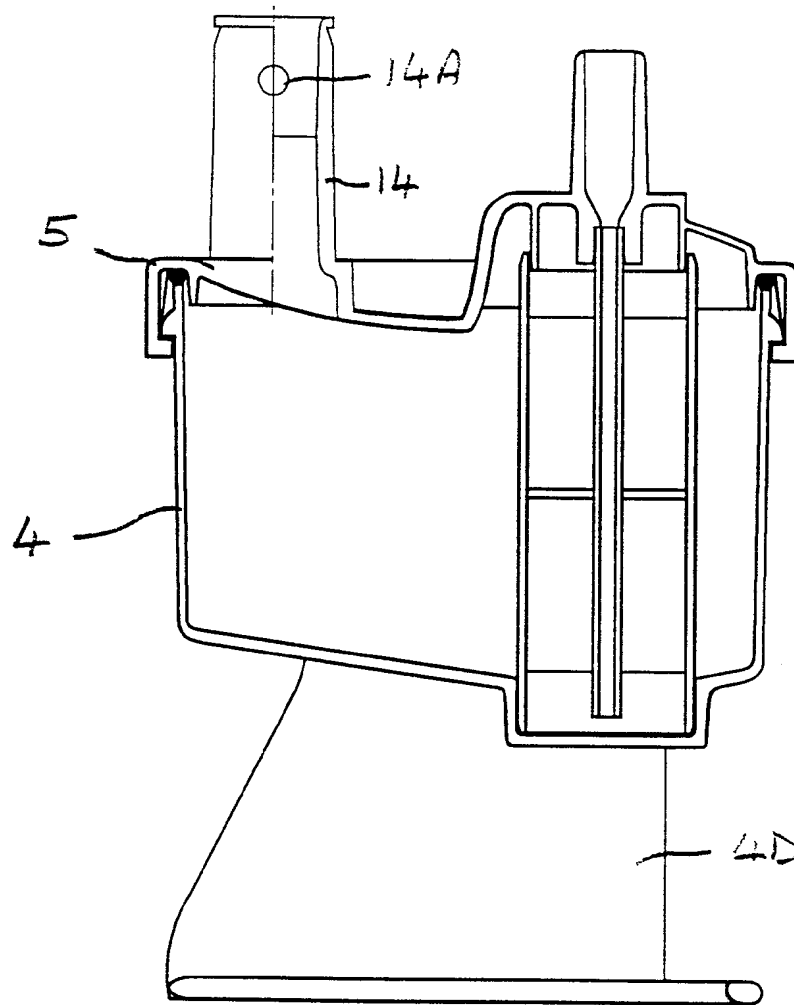
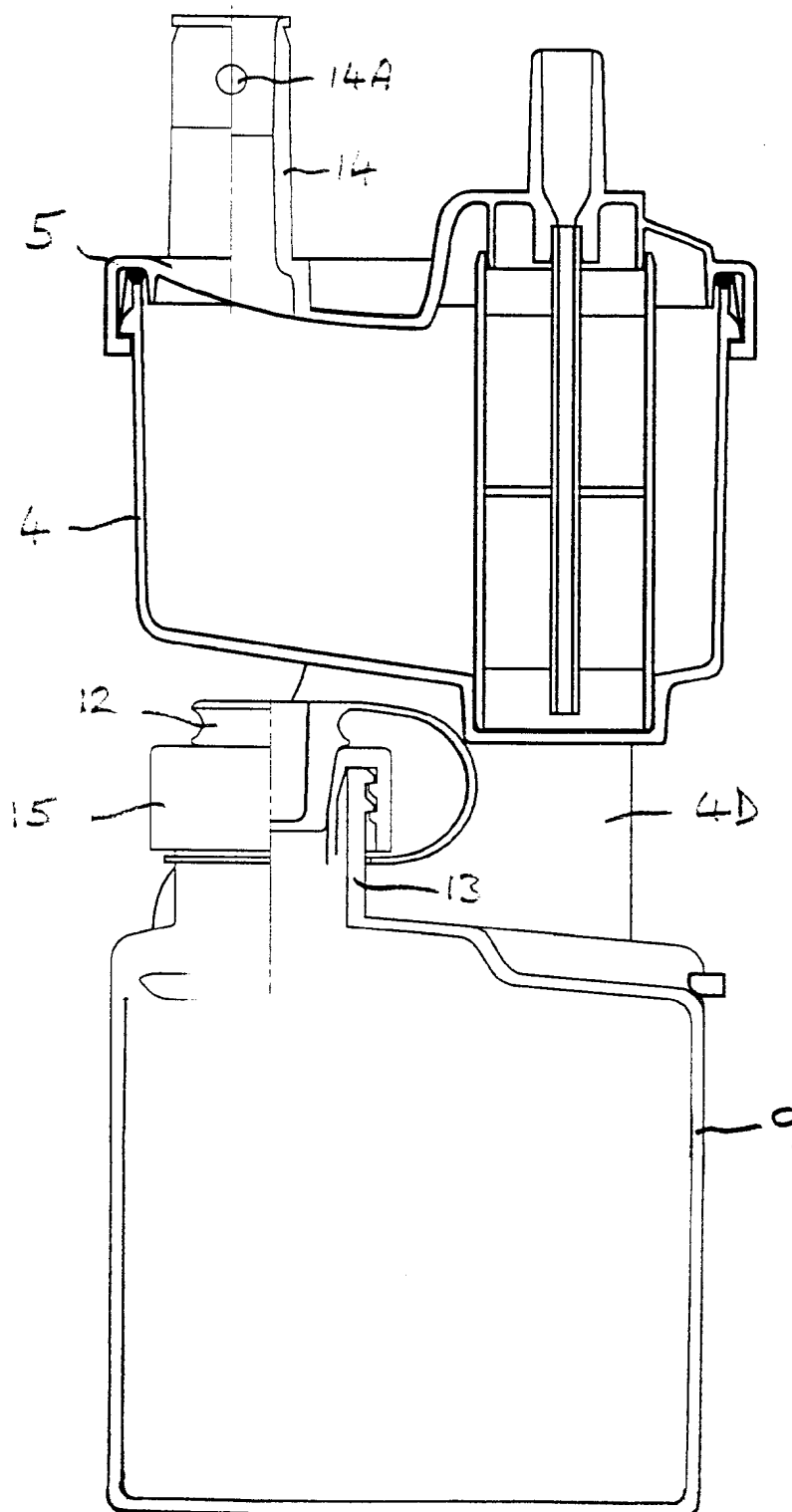
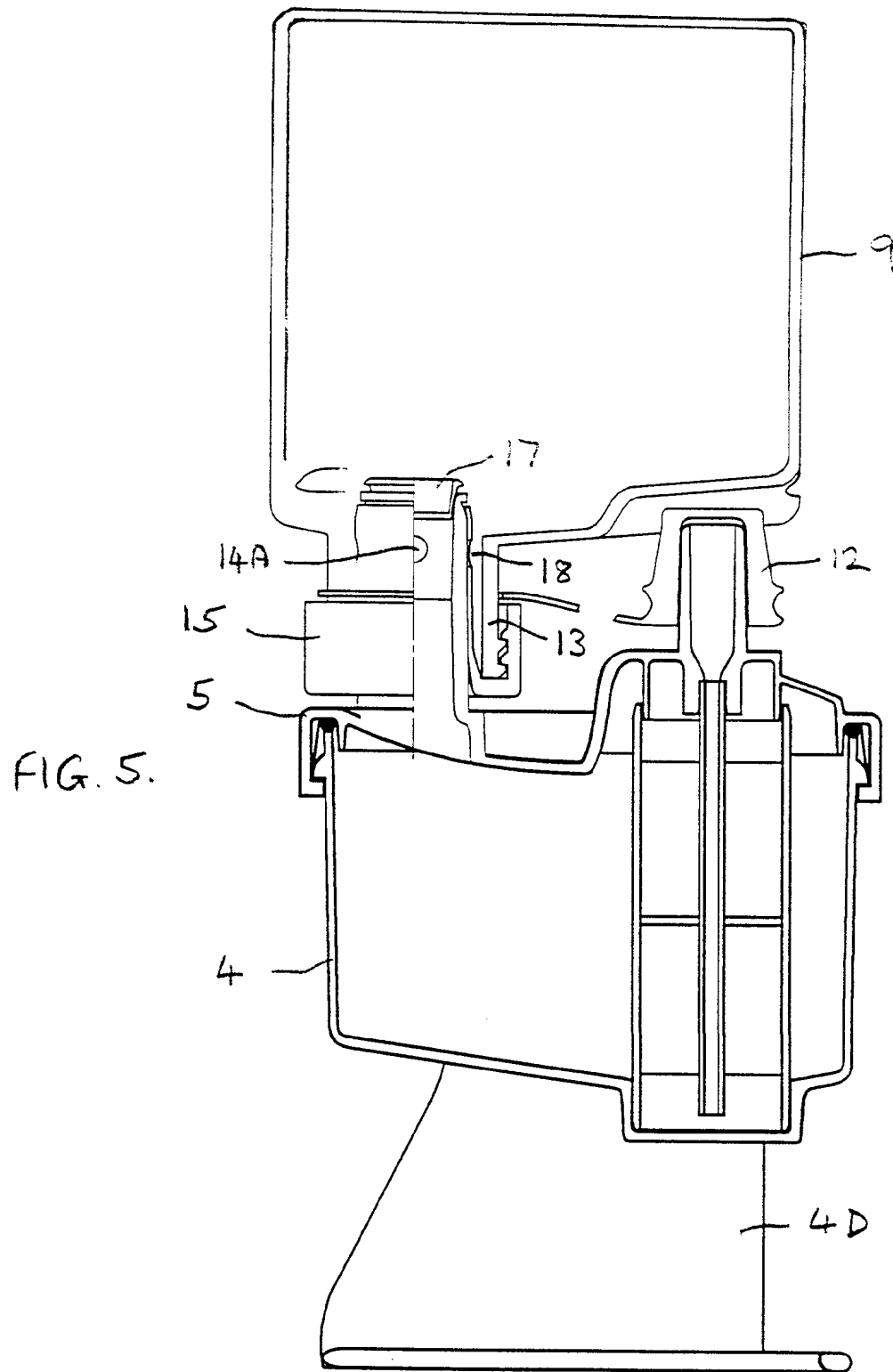


FIG. 3.

FIG. 4







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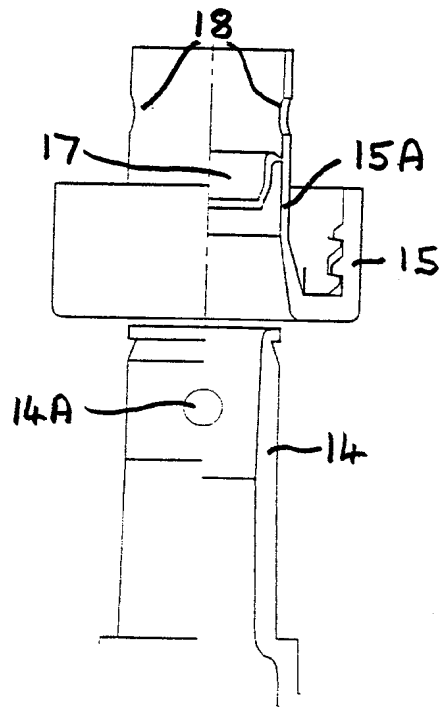


Fig. 6A

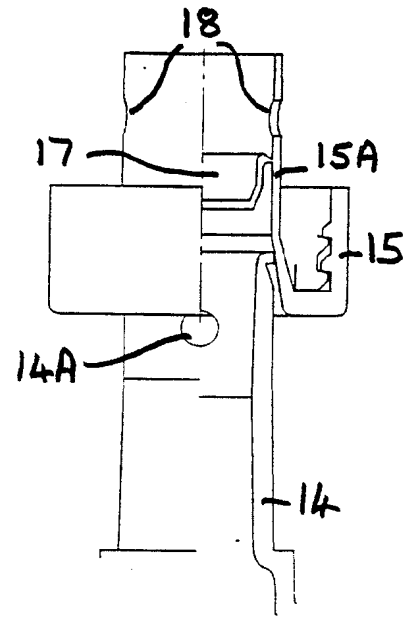


Fig. 6B

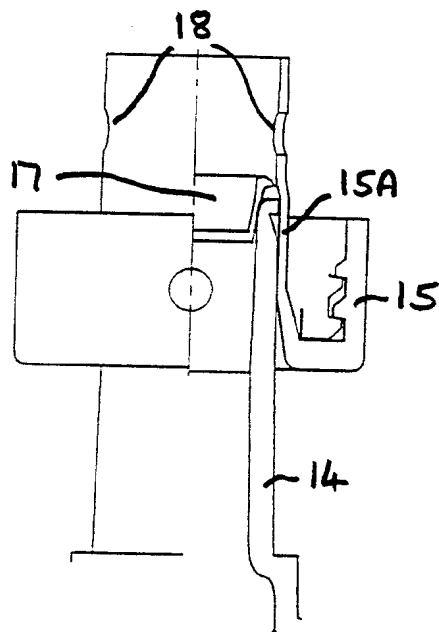


Fig. 6C

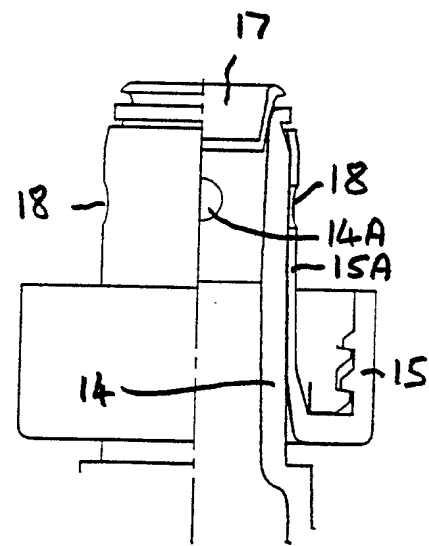


Fig. 6D

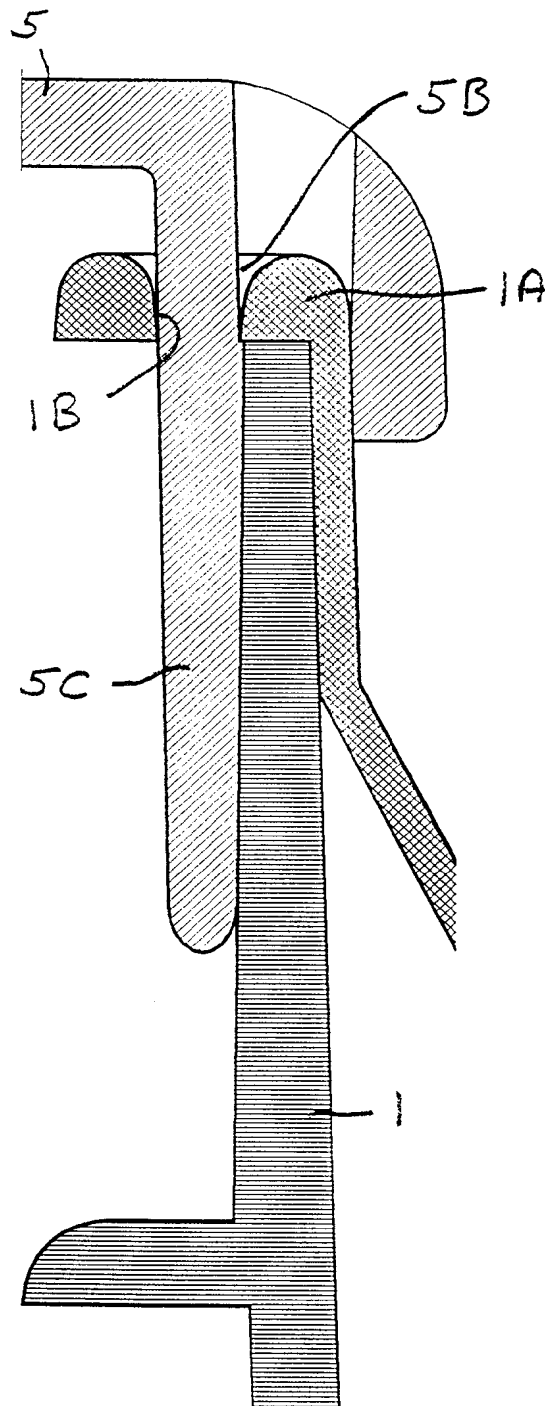


FIG. 7.

# INTERNATIONAL SEARCH REPORT

Inter. .onal Application No

PCT/GB 98/01025

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61M1/00

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61M A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 643 197 A (GREENE ET AL.) 17 February 1987 see column 2, line 29 - column 3, line 9 see column 4, line 26-30; figures ---	1,3-5,7, 9,10
X	DE 89 01 265 U (JOSTRA MEDIZINTECHNIK GMBH & CO KG) 23 March 1989 see page 6, line 5 - page 7, line 9; figures ---	1,4,6-9
X	EP 0 001 718 A (CHINOIN GYOGYSZER ÉS VEGYÉSZETI TERMÉKEK GYÁRA RT) 2 May 1979 see page 10, line 24 - page 12, line 9; figure 2 ---	1,3-7,9
A	US 5 049 273 A (KNOX) 17 September 1991 see abstract; figures --- -/--	1

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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"&" document member of the same patent family

Date of the actual completion of the international search

18 June 1998

Date of mailing of the international search report

01/07/1998

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## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	US 5 624 418 A (SHEPARD) 29 April 1997 see the whole document -----	1,3-9

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB 98/01025

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